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14. ABSTRACT
This award provides core program support to develop key capabilities of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to lead medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Under MD PnP program leadership during the past year, our work informed new AAMI/UL joint standards development; preliminary data from our device clock time study informed an ISO resolution on device clock time accuracy; clinical scenarios from our program were included in work by ISO, AAMI, UL, and ONC/FDASIA WG; UL conducted an STPA hazard analysis related to ICE standard functionality; and we presented at HIMSS13 by the invitation of ONC in their interoperability demo area. We continued collaborating with FDA, NIST, NSF, ONC, DocBox, UMass, Penn, and others, including work on smart alarms initiatives, smart dynamic checklists, certifiable safety of medical device interfaces, and the updated Pre-IDE regulatory submission to FDA.

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Standards and Technology Leadership
Award Number W81XWH-09-1-0705
Principal Investigator: Julian M. Goldman, MD
Period of Performance: 21 September 2012 – 20 September 2013

Introduction

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device "Plug-and-Play" (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. Within a year, we recognized that the need for interoperability encompasses the full continuum of healthcare environments, and we developed a strategy to accelerate the development of interoperability technologies as well as standards. The strategy addressed the need for a "sandbox" laboratory environment to facilitate the testing of devices and technologies with proposed standards; the development of a "plug-and-play" system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors' legal concerns; and assuring the clinical relevance of all proposed interoperability solutions.

TATRC support, through a prior BAA and conference grants, has enabled the MD PnP interoperability program to develop key capabilities, to identify and access numerous available resources, and to build collaborations to achieve MD PnP objectives. TATRC's commitment has enabled us to attract additional program funding from Partners Information Systems, CIMIT, NSF, NIST, and NIH. We have created a medical device interoperability lab at CIMIT in Cambridge, MA, as a multi-institutional, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety and exhibited these at national meetings. We held an international conference on "Improving Patient Safety through Medical Device Interoperability and High Confidence Software", jointly sponsored by TATRC and NSF.

Significantly, core program support from TATRC enabled us to lead and achieve the writing and submission of the first medical device integration system standard – the Integrated Clinical Environment (ICE) standard, Part I, which includes functional architecture and risk mitigation strategies for networked patient-centric interoperable medical devices. In addition, we led a successful collaborative effort of three major healthcare providers to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement by seven medical societies (including the American Medical Association) of medical device interoperability for improving patient safety. We worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. TATRC BAA support has been instrumental in providing "program glue" to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

We planned and co-sponsored with the FDA and Continua Health Alliance a three-day workshop on Medical Device Interoperability in January 2010, attended by over 200 participants from industry, health care, and federal agencies. There has been a follow-on working group meeting regularly, under MD PnP leadership, to address safety and regulatory concerns for integrated medical device systems. The FDA organized another meeting on device interoperability with AAMI in 2011, and in January 2012 the FDA formed a Medical Device

Interoperability Coordinating Council to bring together various groups working on different aspects of interoperability – we continued to play a leadership role in this activity as long as it was still active (until Spring 2013).

Body of Report

The MD PnP Program has become a recognized leader in medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Interoperability will enable the creation of complete electronic health records and will introduce error resistance into networked medical device systems. We are producing a standardization framework consisting of a functional architecture and requirements for implementing standards in a manner that will support interoperability for effective clinical deployment. This requires critical evaluation (or "gap analysis") of potentially suitable candidate standards, as well as the modification of existing standards and development of new standards for implementation in the MD PnP standardization framework. By leveraging available standards, we expect to accelerate the MD PnP standards framework development, so that useful candidate standards can be vetted and demonstrated. This includes partnering with industry and the FDA to define interoperability-related hazards and their mitigations to help inform a regulatory pathway for networked medical device systems, as well as developing the MD PnP Lab as a "sandbox" populated with medical devices and test equipment to serve as a vendor-neutral environment to perform interoperability testing and conformance testing to evaluate proposed standards. Building on what has been accomplished to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards development
- Open clinical platform development
- Clinical and engineering requirements for MD PnP
- Regulatory pathway
- Inclusion of device interoperability in the national health IT agenda

Since the program's inception, more than 900 clinical and engineering experts, and representatives of more than 140 companies and institutions have participated in our plenary workshops / conferences, working group meetings, and focus groups to contribute to ongoing program activities that helped shape the common goals. Our geographically dispersed, interdisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, the VA, FDA, NIST, TATRC, university computer and information science groups at Pennsylvania, Illinois/Urbana-Champaign, Kansas State, New Hampshire, Waterloo (Canada), and Wiener Neustadt (Austria), Draeger Medical Systems, Philips Healthcare, GE Healthcare, Hospira, Intel, DocBox Inc., Moberg Research Inc., Linea Research Inc., Anakena Solutions Inc., LiveData Inc., MITRE Corporation, Lockheed Martin Corporation, IXXAT, Draper Laboratory, NSF/CPS (Cyber Physical Systems), Geisinger Health System, and the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women's Hospital, and Partners HealthCare Information Systems).

For the first Option-Year period of this grant, we proposed the following objectives:

Standards Development
- Continue to convene working and writing groups for subsequent ICE standard parts (Parts II and III for the ICE network controller and device models); manage their work to produce draft standards for submission to ASTM Committee F29

- Expand the gap analysis work of the ICE-PAC group to include additional medical devices and clinical scenarios

Open Clinical Platform Development
- Develop device interface models, working with collaborators, and share requirements with manufacturers
- Coordinate outputs of collaborative projects with NIST, FDA, universities, CIMIT investigators, and industry partners to further open platform development

Clinical and Engineering Requirements for MD PnP
- Develop and deploy a web-based repository of interoperability-relevant clinical scenarios that will facilitate submission of new scenarios and sharing of data
- Continue detailed analysis of the most useful scenarios to define detailed workflows, clinical requirements, and related engineering requirements
- Identify appropriate use cases to include in subsequent ICE parts

Regulatory Pathway
- Publish jointly with FDA a summary of the results of the medical device interoperability workshop
- Work with industry to complete development of a prototype regulatory submission to FDA, as a test case for FDA regulation of systems of integrated medical devices

Facilitated Collaboration (Program Development and Management)
- Develop an enhanced collaborative website for the MD PnP collaborators group to publicly share information.
- Publish on the MD PnP website a second iteration of the MD FIRE contracting language, and work with additional healthcare delivery organizations to adopt MD FIRE
- Stay actively involved with national health IT developments to support inclusion of medical device interoperability on the agenda.

Research Accomplishments

Standards Development, Objective 1: Continue to convene working and writing groups for subsequent ICE standard parts (Parts II and III for the ICE network controller and device models); manage their work to produce draft standards for submission to ASTM Committee F29.

During the past year we continued our foundational work supporting ICE and related standards through multi-organizational working groups such as the Medical Device Interoperability Safety (MDIS) Working Group (see **Objective 9**), the AAMI Ad-Hoc Group on Health Information Technology and Interoperability (AAMI/HITI), the FDA-convened Medical Device Interoperability Coordinating Council (MDICC) (see **Objective 6**), the UL-convened activity working on the AAMI/UL JC2800 joint committee standard for certifiable safety of medical device interfaces, and the new AAMI standards task groups on PCA safety: Integrated Clinical System PCA and Systems Engineering Process. These groups have been heavily informed by MD PnP documents published on our website and through SourceForge. We have drawn on requirements and architecture material from our NIH work to assist the efforts of these groups, which are providing a forum for sharing our learnings from our TATRC work and from our NIH Quantum work relative to the gaps in existing standards and recommendations on how they can be improved. We also shared with DoD our domain expertise on standards and on ICE implementation.

Dr. Goldman chaired the ISO TC121 standards meeting in Shanghai, China in June 2013, where the group passed a resolution (the first of its kind) requiring standards committees to address medical device clock accuracy.

Standards Development, Objective 2: Expand the gap analysis work of the ICE-PAC group to include additional medical devices and clinical scenarios.

The ICE-PAC work was completed in 2012 (see *Annual Report October 2012*).

Platform Development, Objective 3: Develop device interface models, working with collaborators, and share requirements with manufacturers.

Our Device Models working group for the NIH project, in collaboration with NIST, has continued to refine the attributes of device models, including the association (or set-up time) protocol, the real-time communication protocol, and the information or data model. We have had discussions of these requirements for connectivity and interface capabilities with several medical device manufacturers, including St. Jude, Masimo, Mindray, Philips, and Hospira. We continue to update and develop the Medical Device Interface Data Sheets (MDIDS) for point-of-care devices that are most commonly used in hospitals.

A notable event this year was the independent development of an ICE implementation by the medical device manufacturer Draeger. They have shared with our MD PnP team their documentation and executables for this implementation, which was built based on the ICE standard and includes simple device models and device association based on web services. We have been working with Draeger to get this system fully installed and running in our lab. We are strongly encouraging Draeger to release the code for their implementation as open-source, and have offered our expertise to help with dissemination, potentially through the code-sharing environment being developed under TATRC award W81XWH-12-C-0154.

For our analysis of device clock time-stamp data, in September 2012 we received data collected at the Boston VA site, to add to the data previously collected at MGH, Johns Hopkins, and the Hospital of the University of Pennsylvania. After a necessary check of the new data for completeness, and consultation with a statistician, we began data analysis. We have been looking at the results by device type, by networked vs. standalone machines, and by device offset thresholds. We are still considering additional analyses and ways of best displaying the results. We are close to completing the composite analysis and plan to submit a paper based on this work in the next few months. These results will inform device model, system requirements, and standards work. For example, the preliminary data was shared with ISO TC121 to inform the Shanghai resolution on device clock time accuracy.

Platform Development, Objective 4: Coordinate outputs of collaborative projects with NIST, FDA, universities, CIMIT investigators, and industry partners to further open platform development.

We continue to leverage synergies among our projects and our collaborative relationships to ensure that all efforts contribute to the overarching goal of furthering medical device interoperability. This gives us a current understanding of stakeholder needs and requirements, and facilitates project planning. Ongoing standards gap analysis, particularly joint systems engineering analysis with NIST, has been producing recommended updates to existing standards (IEEE 11073 and ICE Part 1). This specific work has transitioned into the open-source code dissemination environment that we are developing under TATRC award W81XWH-12-C-0154.

We held an open house at our MD PnP Interoperability Lab on October 31 2012 in conjunction with the Fourth Annual Medical Device Connectivity Conference. Some forty visitors from health care and industry saw demonstrations related to our NIH and TATRC projects. By popular demand, we held a second session on November 2nd and had another 20 visitors, including one from DoD. These demos were shown to visitors from NIH on November 16th and 20th.

For these open houses, Intel provided prototype hardware used in our 2012 collaborative study on the impact of integrated medical devices on hospital IT networks. This work has helped to clarify functional requirements for the ICE Network Controller and ICE External Interface, as well as safety requirements for the PCA scenario, such as the maximum number of pumps that can be managed reliably by a control application in an integrated clinical environment. This project has also helped Intel with requirements for their roadmap, which will support adoption of device interoperability.

We held another set of open houses on September 24-26 2013, and hosted some 50 visitors, including the IEEE 11073 group from HL7, the Open Health Tools Board of Directors and new members, and clinicians and biomedical engineers from MGH.

Clinical and Engineering Requirements, Objective 5: Develop and deploy a web-based repository of interoperability-relevant clinical scenarios that will facilitate submission of new scenarios and sharing of data.

Requirements for the use case repository based on experience with the early prototype were finalized and documented. This objective has been completed for purposes of this award. This work has transitioned to TATRC award W81XWH-12-C-0154, where we are building a more robust web-based implementation of the use case repository that can be tested and deployed.

Clinical and Engineering Requirements, Objective 6: Continue detailed analysis of the most useful scenarios to define detailed workflows, clinical requirements, and related engineering requirements.

The clinical use cases we have collected are being used as highly-valued input for work by our industry and university collaborators, and several archetypal use cases representing different aspects of interoperability were included in Annex B of the ICE standard, Part I (ASTM F-2761-09). Our use cases have typically included a much higher level of detail and specificity than any we have seen from industry and other sources.

As part of our participation in the FDA-sponsored Medical Device Interoperability Coordinating Council (MDICC) in 2011-2012, Dr. Goldman chaired the committee on Clinical Needs & Clinical Landscape for Interoperability. This group collected clinical scenarios related to interoperability, and in support of that effort we posted on our mdpnp.org web site a template based on the clinical scenarios in the ICE standard. We maintained an index to the scenarios contributed by various sources, and may eventually add some of these to our repository (see **Objective 5**).

Four use cases that are intended to represent a broad spectrum of interoperability requirements were selected for our NIH Quantum project: (1) Medication safety interlock, exemplified by Patient Controlled Analgesia (PCA) infusion pump safety interlock; (2) Optimization of Intensive Care Unit (ICU) preparedness for patient transfer from OR, exemplified by preparing the ICU (devices, medications, personnel) to receive a post-op patient after cardiac surgery; (3) Use of telehealth devices when a patient enters the hospital, especially to demonstrate creation and management of data and creation of vital signs alarms by the ICE supervisor apps; and (4) Sedation during Endoscopy, demonstrating safety and effectiveness implications of deploying

increasingly complex interoperable medical device systems. The detailed workflow analyses for these scenarios are being shared on our mdpnp.org website as they become available.

The activity of identifying and refining high-level clinical scenarios, as a foundation for developing technical specifications for medical device interoperability, is ongoing. This TATRC grant enables us to organize requirements across multiple projects and sources – NIH, FDA, ONC, NSF, etc. – to pull together and vet information that will facilitate adoption by the DoD, the VA, and device manufacturers. Collaborative work with DocBox Inc. is contributing to the refinement of related project-specific clinical requirements and use cases, including detailed workflow and requirements from an engineering perspective. This work is providing additional details of workflow for the scenario repository (see **Objective 5**), as well as for the engineering requirements being developed under our NIH Quantum grant.

Clinical and Engineering Requirements, Objective 7: Identify appropriate use cases to include in subsequent ICE parts.

Current work with collaborators – including the Medical Device Interoperability Safety Working Group, NIST, and various companies – is identifying use cases that could be included in subsequent parts of the ICE standard. However, this work is no longer limited to ASTM. We are including use cases in ISO, AAMI, joint AAMI/UL, and the ONC FDASIA Workgroup (Food and Drug Administration Safety Innovation Act – see **Objective 12**) work now, including some that may subsequently be useful for further development of the ICE standard. A new use case emerging from our NIH Quantum work is one for device management, including setting up and configuring ICE systems. Device management is an issue of considerable interest to the clinical and biomedical engineering communities. Managing different versions of device, application, and infrastructure software – as these are being constantly updated by a variety of manufacturers – is a complex issue that will influence the design of the ICE supervisor and other components.

Regulatory Pathway, Objective 8: Publish jointly with FDA a summary of the results of the medical device interoperability workshop.

Completed (see *Annual Report October 2012*). All talks and slides, as well as transcripts, from the workshop were published on the web (our mdpnp.org website contains links to material on the FDA website) – this constitutes publication per the intent of this objective.

Regulatory Pathway, Objective 9: Work with industry to complete development of a prototype regulatory submission to FDA, as a test case for FDA regulation of systems of integrated medical devices.

Our leadership of the Medical Device Interoperability Safety Working Group, or MDISWG (formerly the Prototype Regulatory Submission working group: 20 participants from industry, clinical care, standards development organizations, and regulatory agencies) resulted in industry consensus on the ICE approach as desirable for the Pre-IDE submission. The MDISWG submitted the Pre-IDE document in February 2012, and had a successful face-to-face meeting with the FDA that April. With preliminary agreement from the FDA on the core approach of this submission, the MDISWG has continued to refine the document, now referred to as the "pre-submission," which will then be resubmitted for an official response.

At that time we plan to put this document in the public domain by publishing a summary article in a regulatory journal and making the full pre-submission available on our mdpnp.org website as a reference. As an interim step, a paper describing our findings related to regulatory issues

was accepted for publication by *Anesthesia and Analgesia* as part of a section devoted to publications from the June 2012 meeting on Innovations and Applications of Monitoring Perfusion, Oxygenation and Ventilation. The publication included an FDA author, and upon additional internal FDA review, is being held back from publication pending revision.

Information about the work on this prototype regulatory submission has been shared in other FDA meetings where Dr. Goldman has provided expert input (AAMI, UL, FDASIA Workgroup – see **Objective 12**, FCC mHealth Working Group), as well as with our NIH sponsors.

To further the progress in both the regulatory area and in interoperability standards (**Objective 1)**, we engaged UL to perform a "STPA/STAMP" hazard analysis related to the ICE standard functionality, which is expected to enable both the application of the ASTM-F2761 standard and the development of the UL2800 and AAMI standards. The results of this study will also inform our NIH Quantum work.

UL was able to engage a senior engineer at the FDA to participate in this analysis. As part of this work, UL has validated the consistency of the results of their literature search with the current state of STPA/STAMP research, and has concluded that STPA/STAMP fits within the framework of the Hazard-Based Safety Engineering process. UL has also reviewed recent FDA revisions to STPA analysis, regarding control structures and mitigation strategies. A preliminary report on this analysis is currently being reviewed and edited by the UL, FDA, and MD PnP teams involved. We expect to have a final version for publication within the next quarter.

Program Development, Objective 10: Develop an enhanced collaborative website for the MD PnP collaborators group to publicly share information.

After exploring various options, we decided to work with Open Health Tools (OHT) as an environment for publicly sharing materials and work products that we develop. We have established a medical device interoperability "project" area on OHT, and we are continuing to discuss what kinds of documents and tools we will want to share. At the HIMSS12 conference in Las Vegas, our team members attended technical and management sessions presented by OHT and made good contacts among existing OHT members.

We have pursued several options for public sharing of our project work products with collaborators and others. As part of updating our mdpnp.org website, we set up an area for open source sharing on SourceForge, a web-based community of over 300,000 open-source projects and toolsets with capabilities that match our needs. We uploaded our existing code to SourceForge and have continued to do that as code becomes available for sharing. We have been quite pleased with SourceForge as a platform for collaborative development, and are using it also for binary distributions designed for easy deployment, discussion forums, a wiki, and issue ("ticket") tracking. Activity on the site over the past seven-plus months has been rewarding (see Figure 1 below). Increasing adoption of SourceForge and meeting new collaborators through it will be major areas of focus for us in the next few years.
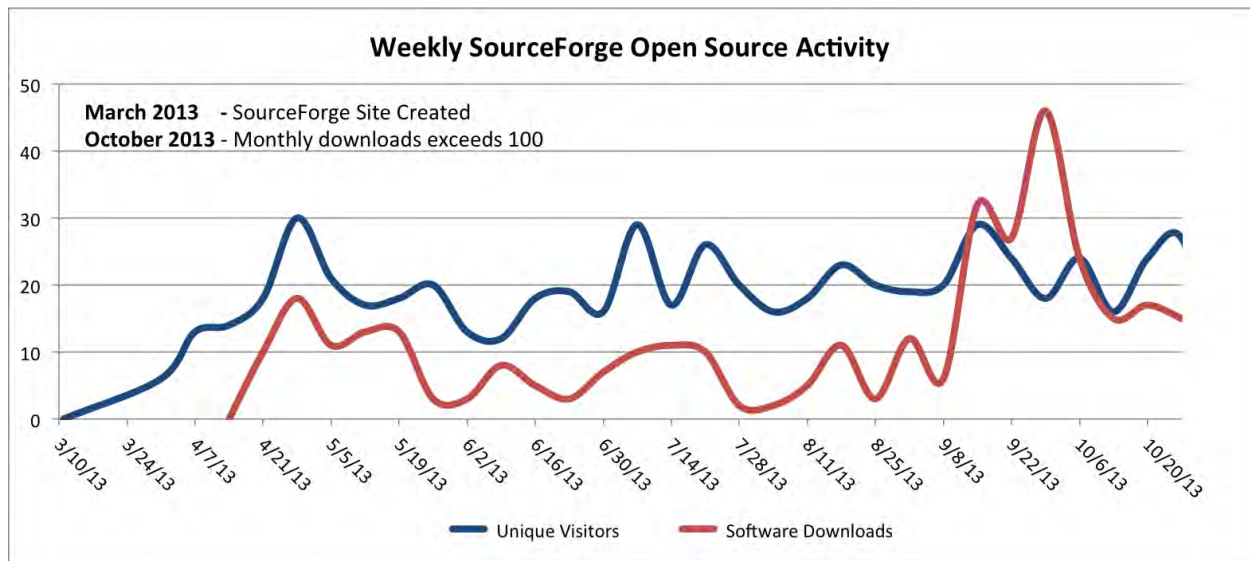
Figure 1: Weekly Open Source Activity on MD PnP SourceForge Site

We also established a medical device interoperability "project" area on Open Health Tools (OHT) as an environment for publicly sharing materials and work products that we develop, and we are continuing to discuss what kinds of documents and tools we want to share there.

Program Development, Objective 11: Publish on the MD PnP website a second iteration of the MD FIRE contracting language, and work with additional healthcare delivery organizations to adopt MD FIRE.

Part 1 was completed for purposes of this award, as Version 2.0, signed by the VA, was published on the mdpnp.org website in September 2012. We continue to work with additional organizations, including internationally, as opportunity allows, on updates to the MD FIRE contracting language. In addition, our NIH External Advisory Committee has recommended that we incorporate learnings from our Quantum project in providing some more specific language within MD FIRE.

In parallel, Dr. Goldman has continued to provide assistance to DoD in exploring acquisition options to standardize medical device interface capabilities.

Program Development, Objective 12: Stay actively involved with national health IT developments to support inclusion of medical device interoperability on the agenda.

During the past year, the MD PnP program has continued to work closely with the FDA, NIST, NSF, the Office of the National Coordinator for Health IT (ONC), and other federal agencies on advancing medical device interoperability. Recognition of the critical role of device interoperability in the national health IT agenda continues to increase, as evidenced by the attendance of more than 65 representatives of government agencies at the series of demonstrations of our work that we held in the Washington DC area in August 2013.

The relationships stemming from the adoption of our NIH/NIBIB grant by the ONC as an affiliate of the ONC-funded SHARP (Strategic Health IT Advanced Research Projects) program resulted in the involvement of MD PnP in a "Pan-SHARP" project on medication reconciliation. By integrating infusion pump data into the project, we educated the SHARP grantees and ONC on

important attributes of device data for the EHR and subsequent analysis of EHR data. Phase I of this project was completed in late summer 2012, and the results were presented by a panel, in which Dr. Goldman participated with other SHARP leaders, at the AMIA conference in November 2012 (planned again for AMIA 2013 in November). A paper on the ONC "Pan-SHARP" project has been developed over the past year and has just been submitted to JAMIA for publication.

Dr. Goldman was invited to the FCC Chairman's mHealth Summit in June 2012 to represent wireless healthcare interoperability needs, and was asked by the Chairman to be one of three co-chairs of the "mHealth Task Force" set up to develop recommendations for industry and government action to harness the potential of mobile devices to improve health outcomes and lower costs of care. In September, the Task Force released its findings and recommendations, which were presented at the Information Technology and Innovation Foundation (ITIF) panel discussion on the FCC mHealth Task Force, co-chaired by Dr. Goldman. This relationship with the FCC continues to evolve.

Dr. Goldman's participation in the December 2012 IOM meeting on Systems Approaches for Improving Health Innovation provided an opportunity to share information about our body of work with a large senior leadership group, and led to an important connection with the Betty & Gordon Moore Foundation, which was interested in learning more about our interoperability work. We had several calls with their Patient Care group and a successful site visit where we presented a proposed plan for bringing an interoperable solution for PCA safety to clinical testing. Although Moore decided it could not fund the entirety of our proposal at the present time, they are interested in talking with us further about potential funding opportunities.

Dr. Goldman was invited in April 2013 to serve on the new Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup, which was charged with "providing expert input on issues and concepts identified by the Food and Drug Administration (FDA), Office of the National Coordinator for Health IT (ONC), and the Federal Communications Commission (FCC) to inform the development of a report on an appropriate, risk-based regulatory framework pertaining to health information technology including mobile medical applications that promotes innovation, protects patient safety, and avoids regulatory duplication." Dr. Goldman is co-chair of the Regulations Subgroup, and has been able to share with this group some of the important findings from our research, as evidenced by inclusion of safe medical device interoperability and exemplar use cases in the interim briefings and final report to the ONC HIT Policy Committee (http://www.healthit.gov/facas/sites/faca/files/FDASIARecommendationsDraft030913_v2.pdf).

At HIMSS13 in March 2013, we applied for and were granted a kiosk as part of the ONC's area in the Interoperability Showcase. We demonstrated the transfer of a patient's device settings from an ICE system in the OR to an ICE system in the ICU as part of preparing to receive the patient (this is one of our NIH Quantum scenarios – see Figure 2 below). The demo showed reading and changing of device settings, external query via CONNECT to the TATRC test EMR, coordination between multiple apps, and coordination via CONNECT between a commercial ICE implementation and a research / rapid prototyping ICE implementation. The demo was highly successful – unique in the ONC area, where other demos showed interoperability of EHRs – and got high praise from Farzad Mostashari, the National Coordinator for Health IT. Dr. Goldman also presented a talk on "Medical Device Interoperability: 'a wicked problem'" attended by over 100 conference participants. More information on our HIMSS demonstration can be found at http://mdpnp.org/MD_PnP_at_HIMSS_13.html.
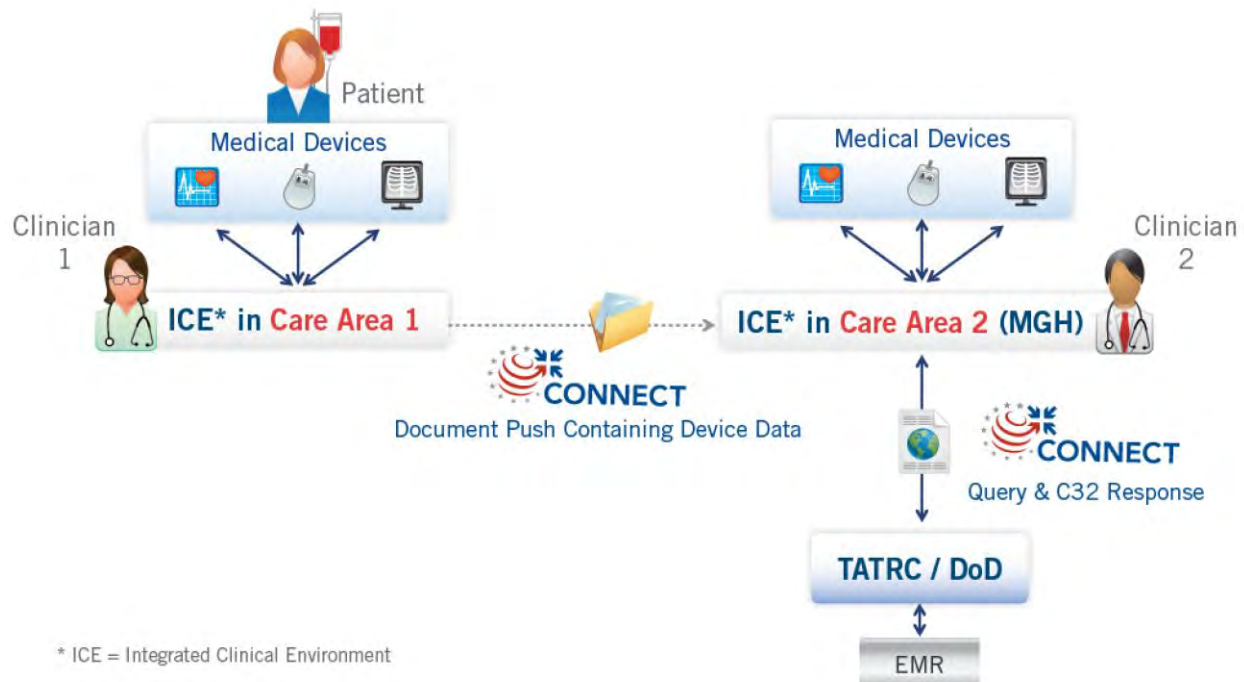
Figure 2: Overview of the Demonstrated Scenario, Connections, and Flow at HIMSS13

Our work was foundational for the formation of two major standards efforts that kicked off during Spring 2013. The UL2800 work we have been involved with for the past year has become an AAMI/UL joint committee that was launched at the AAMI standards week meeting in June 2013. This committee includes most (if not all) of the stakeholders for interoperability, including device manufacturers, DoD, FDA, several SDOs, and Dr. Goldman initially representing clinical community requirements.

In parallel with the JC2800 Joint Committee, AAMI launched two PCA safety task groups charged with identifying best practices for use case and app development, using PCA as an initial clinical scenario. We have provided these groups with several years' worth of previous work, much of it funded by TATRC. This is an important pathway for clinical and manufacturer adoption of our work.

Dr. Goldman has been part of a group convened by the Brookings Institution to discuss capturing unique device identifiers (UDIs) in administrative health care claims. As part of the UDI Implementation Work Group, we have implemented and tested an initial UDI for ICE and will update this work now that the FDA has issued its final rule on UDIs. (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification)

Following our successful technology demonstrations to federal agencies in August, Dr. Goldman was an invited participant at TATRC's September 2013 interagency meeting related to medical device interoperability, to further explore an adoption pathway based on DoD clinical use cases.

Key Research Accomplishments

- **Standards work related to medical device interoperability.** We have leveraged our foundational work on the ICE standard (ASTM F2761-09) to bring those concepts into other related standards work. We have been actively involved in the AAMI/UL2800 joint committee standard for certifiable safety of medical device interfaces, and the new AAMI standards task groups on PCA safety. We have drawn on requirements and architecture material from our TATRC and NIH work to assist the efforts of these groups, which are providing a forum for sharing our learnings from our projects relative to the gaps in existing standards and recommendations on how they can be improved.

- **Interoperability procurement language.** In June 2012 the VA signed onto the MD FIRE (Medical Device Free Interoperability Requirements for the Enterprise) interoperability procurement guide, joining the original contributing institutions – Kaiser Permanente, MGH/Partners HealthCare, and Johns Hopkins Medicine – that under MD PnP leadership issued a call for action in October 2008 to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. This sample procurement language has been shared with many organizations and is currently being reviewed by several groups for potential adoption. The latest version reflects input from the VA and is available on the MD PnP website (http://mdpnp.org/mdfire.php).

- **Regulatory pathway.** The MD PnP program has from its inception worked closely with the U.S. FDA to identify a regulatory pathway that will support the MD PnP concept – one which will not require re-validation or re-clearance of an entire networked system as each new independently validated device is added to the medical network. Over the past eight years we have studied and elaborated the issues and solutions surfaced by medical device interoperability stakeholders. An important step towards FDA buy-in was the three-day workshop on medical device interoperability planned by the MD PnP program in conjunction with the Continua Health Alliance and the FDA and held at the FDA in January 2010. This workshop brought together over 200 participants from stakeholder communities to explore the issues and roadmap potential solutions (http://mdpnp.org/FDA_Workshop.html).

  As follow-up to the workshop, a working group comprised of companies, standards organizations, clinical and legal participants, and the FDA has met weekly to work on the development of a prototype regulatory submission of an interoperable medical device system. This group handed off its work products to the FDA in Spring 2011, for further internal development at FDA, and has continued to meet under Dr. Goldman's leadership as the Medical Device Interoperability Safety (MDIS) working group. The MDIS further developed these concepts and completed a pre-IDE document, submitted to the FDA in February 2012 and discussed in a face-to-face meeting with the FDA that April. Updates to the document in response to FDA feedback are being completed, and the revised document will be submitted to FDA within the next quarter and then published on the mdpnp.org website.

- **Safety certification pathway.** The MD PnP program's collaboration with UL has resulted in mutual contributions to our ICE architecture designs and their new proposed standard (UL 2800) for certifiable safety of medical device interfaces.

- **Medical society endorsements/end-user "pull".** From March 2007 to June 2009, through MD PnP program leadership, the need for medical device interoperability was

endorsed by 16 medical societies – including the American Medical Association, Anesthesia Patient Safety Foundation, the American Society of Anesthesiologists, the Society of American Gastrointestinal Endoscopic Surgeons, the World Federation of Societies of Anaesthesiologists, the Society for Technology in Anesthesia, and the Massachusetts Medical Society. These endorsements continue to be a powerful motivator for other groups considering deeper engagement. Example text:

> *Intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. We also recognize that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit.*

- **Collaborative R&D.** The Joint Workshop on High Confidence Medical Devices, Software, & Systems (HCMDSS) and MD PnP Interoperability, funded by TATRC and NSF and held in June 2007, led to extensive collaborations with the University of Pennsylvania and the University of Illinois at Urbana-Champaign. The Cyber Physical Systems program at NSF has funded each of them to work with our program to investigate safety-critical aspects of networked medical device systems. NSF awarded a five-year grant in 2010 to University of Pennsylvania that is synergistic with MD PnP efforts. NIST has recently collaborated on ICE Data Logger development, and we are working with DocBox Inc. on DoD-funded ICE development. Our work with DoD/TATRC SBIRs and with other collaborators has informed research priorities for NSF and other agencies.

- **CIMIT MD PnP Lab**. The CIMIT MD PnP Interoperability Lab opened in May 2006 to provide a vendor-neutral "sandbox" to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. The Lab has been used by our collaborators to further develop demonstrations of interoperability-based patient safety improvements (improving the safety and quality of portable x-rays and of patient-controlled analgesia systems that are used for pain management). We have ongoing work in the Lab on our NIH project and with NIST and other investigators, and we intend to host additional inter-institutional projects there. We have held several Open Houses to show our work to others, we recently initiated a Visiting Scholar-in-Residence program with an anesthesia resident from Columbia-Presbyterian, and we are holding an MIT-Harvard "Hacking Medicine" hackathon there in November. Lab tours are provided on a frequent ad-hoc basis, with visitors from industry, standards organizations, federal agencies, and healthcare institutions.

- **Relationships with federal agencies.** In addition to the FDA, the MD PnP program has been working with NIST, NSF, the Office of the National Coordinator for Health IT, the VA Office of Joint Interoperability Ventures, and the Office of Science & Technology Policy (OSTP) at the White House. Recognition of the critical role of device interoperability in the national health IT agenda has continued to increase over the past year, as evidenced most recently by the 65+ representatives from federal agencies (including FDA, ONC, NIST, NIH, OSTP, and NSF) who attended a series of demonstrations of our work, hosted by NIH in August.

- **Non-DoD Funding.** In October 2012 we received a 3-year $500K grant from NSF, to support the University of Massachusetts in its 3-year grant from NSF Cyber Physical Systems.

In addition to the specific achievements above, the MD PnP program has continued to gain increasing traction through our collaborative relationships. The web of connections among people in our community of interest continues to generate new connections to supportive individuals in government agencies, healthcare institutions, and other organizations who are helping to further the aims of the program. During the past year, CIMIT continued to provide space for the MD PnP Lab and for ten program offices.

Reportable Outcomes

175+ Meetings:

- October – December 2012 – Monthly teleconference calls of the Unique Device Identifier (UDI) Implementation Work Group
- October – December 2012 – Monthly teleconference calls of the Medical Device Innovation, Safety and Security Consortium (Healthcare Delivery Organizations group)
- October 2012 – March 2013 – 11 teleconference calls for the FCC mHealth Task Force
- October 2012 – June 2013 – 12 teleconference calls for the FDA Medical Device Interoperability Coordinating Council (MDICC) activity
- October 2012 – September 2013 – weekly teleconference calls of the Medical Device Interoperability Safety (MDIS) working group (successor to the PRS, the Prototype Regulatory Submission working group) to refine the Pre-IDE submission to FDA
- October 1 2012 – FDA MDICC face-to-face meeting, Washington, DC
- October 15 and December 13 2012 – UDI face-to-face meetings at Brookings Institute, Washington, DC
- December 3-5 2012 – mHealth Summit, Washington, DC
- December 6-7 2012 – AAMI Ad-hoc Group on Health Information Technology and Interoperability, via teleconference
- December 10-12 2012 – Chaired standards meetings of ISO TC121, Cambridge, MA
- December 14 2012 – Institute of Medicine meeting on Systems Approaches for Improving Health Innovation, Washington, DC
- January – March 2013 – 5 meetings or teleconference calls for the UL project
- February 26 2013 – UDI Implementation Work Group webinar
- March 1 2013 – Meeting with UL, Chicago, IL
- March 3-7 2013 – HIMSS13 Conference, New Orleans, LA (participated by invitation in ONC booth in Interoperability Showcase)
- March 18 2013 – UDI Workshop at Brookings Institute, Washington, DC
- April – June 2013 – Weekly teleconference calls of the AAMI / UL Joint Committee working on the 2800 standard
- April – September 2013 – 10 MD PnP lab demonstrations for device manufacturers and standards groups
- April – September 2013 – 24 teleconference calls of the HIT Policy Committee's FDASIA Workgroup
- April 26 2013 – FCC Consumer Advisory Committee meeting, Washington, DC
- May 5-7 2013 – UL Health Sciences Council Meeting, Chicago, IL
- May 30-31, August 7, September 4 2013 – Face-to-face meetings of the HIT Policy Committee's FDASIA Workgroup, Washington DC

- June 1-3 2013 – AAMI Standards Week, Long Beach, CA
- June 4 2013 – Meeting of the AAMI Alarm Steering Committee
- June 13-21 2013 – Meeting of ISO TC121 Anaesthetic and respiratory equipment standards committee, Shanghai, China
- July – September 2013 – 7 teleconference calls on MDIS working group and AAMI/UL 2800 coordination
- July – September 2013 – Weekly teleconference calls for the MGH-UL project on STPA/HBSE analysis of risk controls involved with PCA
- July 18 2013 – planning call for AAMI HTSI Alarm Webinar Series
- August 1 2013 – FDA Telcon on Mobile Medical Apps
- August 2 2013 – FCC Consumer Advisory Committee meeting, Washington, DC
- August 21-22 2013 – MD PnP technology demonstrations at NIH for federal agencies
- September 1-5 2013 – OR.Net workshop at GMDS (Medical Informatics conference) and collaborative work on ICE implementations at Dräeger, Lübeck, Germany
- September 10 2013 – Panel on Smart Healthcare Technologies for NSF SBIR/STTR program, Arlington, VA
- September 12 2013 – Meeting of the DoD JPC1 HIT working group, Washington, DC

19 Presentations on Medical Device Interoperability Topics:

Dr. Goldman delivered invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency to the following groups during the past year:

- October 2-3 2012 at FDA / AAMI Interoperability Summit, Herndon, VA
- October 4 2012 Panels at the NSF CPS Medical Session, Washington, DC
- October 25 2012 at NSF Time Workshop, Baltimore, MD
- October 31 2012 MD PnP Lab Open House, Cambridge, MA
- November 2 2012 Keynote and Panel at Medical Device Connectivity Conference, Boston, MA
- November 4 2012 Panel at American Medical Informatics Association (AMIA), Chicago, IL
- November 5 2012 at University of Illinois at Urbana-Champaign, Urbana, IL
- November 29 2012 Panel at the Wireless Connectivity in Medical Devices Conference, Boston, MA
- December 3 2012 at mHealth Summit, Washington, DC
- January 10 2013 Panel lecture at Society for Technology in Anesthesia annual conference, Phoenix, AZ
- February 16 2013 at Annual Meeting of the American Association for the Advancement of Science, Boston, MA
- February 22 2013 at Cost-Effectiveness Symposium, Woodstock, VT
- March 7 2013 Education session at HIMSS13 Conference, New Orleans, LA
- May 6 2013 Panel presentation at UL Health Sciences Council Meeting, Chicago, IL
- May 20 2013 Visiting Professorship at Tufts Medical Center, Boston, MA
- May 20 2013 Medical Grand Rounds at Geisinger Health System, Danville, PA
- September 16 2013 Keynote at AHIMA Health Information Integrity Summit, Alexandria, VA
- September 17-18 2013 – Lecture and panel at meeting of the Anesthesia Patient Safety Foundation, Phoenix, AZ

MD PnP Lead Technical Engineer, Dave Arney, delivered the following presentation on medical device interoperability topics during the past year:

- September 30 2013, "Challenges and Research Directions in Medical Cyber-Physical Systems" at CERIST International Autumn School on Cyber Physical Systems, Algiers, ALGERIA

Web Site:

- www.mdpnp.org is maintained as a major communication vehicle for the program and had a major redesign this past year – provides access to ICE standard, MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop, and downloads of sharable documents and code – receives about 1,000 visits per week

Manuscripts/Publications:

    None

Funding Applications Facilitated by this BAA to Date (total costs shown):

- Funded: CIMIT: $51K for FY10 program leader support
- Funded: CIMIT: $51K for FY11 program leader support
- Funded: CIMIT: $25K for FY12 program leader support
- Funded: CIMIT: $98K for FY11 support for development of a pre-clinical PCA closed-loop control application
- Funded: CIMIT: $98K for FY11 support for interoperability of portable x-ray devices with ventilators in an ICU at a VA hospital (collaboration with VA Boston)
- Funded: CIMIT: $98K for FY11 support for development of a clinical algorithm-driven interoperable smart ventilator (collaboration with Boston University)
- Funded: CIMIT: $98K for FY12 support for prototype demonstration of veterans health data exchange between 3 EHR systems (collaboration with VA HITIDE, TATRC, and NwHIN)
- Funded: TATRC: $70K for MD PnP subcontract on Moberg Research SBIR Phase II award
- Funded: TATRC: $100K for MD PnP subcontract on DocBox Inc. award
- Funded: TATRC: $785K contract for enabling medical device interoperability for the Integrated Clinical Environment
- Funded: TATRC: $764K for Option-Year 1 of contract for enabling medical device interoperability for the Integrated Clinical Environment
- Funded: TATRC: $445K for Year 1 of MD PnP subcontract on DocBox Inc. award
- Funded: NIST: $100K for evaluation of ICE functional requirements for medical device interoperability (standards gap analysis)
- Funded: NSF: $620K for MGH subcontract on University of Pennsylvania 5-year award for assuring safety, security, and reliability of medical device systems
- Funded: NSF: $500K for MD PnP subcontract on University of Massachusetts CPS collaborative research award
- Funded: NSF: $49.2K conference grant for CPS Workshop Planning Meeting
- Funded: NIH/NIBIB: $9.9M for 5-year development of prototype healthcare intranet, an open ICE platform
- Not Funded: Office of Naval Research: $11.6M for 5-year development of prototype acute critical care system of integrated medical devices for safer, monitored transport of wounded warriors from battlefield to care facility

Other: In-kind engineering support and/or contribution of equipment for the lab from Draeger Medical, Philips Healthcare, FDA, Draper Laboratory, Kaiser Permanente, University of Pennsylvania, LiveData Inc., DocBox Inc., and Intel (valued at over $500,000 to date).

Conclusions

As with prior TATRC BAA support, this BAA has provided core program support that enables the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to provide important clinically focused national leadership of the growing move towards open standards and related technologies for networking medical devices to support clinical solutions for improving patient safety and healthcare efficiency.

Notable achievements enabled or facilitated by this multi-year TATRC support include:
- The MD PnP Lab is on track to becoming a test bed for use by other hospitals, researchers, device manufacturers, regulators, standards developers, and federal agencies to access technology, domain expertise, open-source software, and medical devices and data to accelerate innovation in the fields of medical device interoperability, healthcare Systems Engineering, patient safety, standards development, process re-engineering, clinical decision support, and more.
- We led the development of an international standard (ASTM F2761) for the Integrated Clinical Environment (ICE) and saw it through to adoption and publication by ASTM International;
- Three major healthcare delivery systems collaborated on shared interoperability contracting language under MD PnP program leadership, and a second iteration of this language was signed last year by the VA;
- Sixteen medical societies (including the AMA) have endorsed the need for medical device interoperability;
- The FDA published regulatory guidance on Unique Device Identifiers (UDI) for medical devices. Our program has informed the current regulations and the expected expansion to include network readability of the UDI;
- Strong collaborations have been established with a broad spectrum of federal agencies, putting safe medical device interoperability on the healthcare agenda;
- We contributed healthcare organization needs to the FCC in preparation for a wireless test bed they are planning;
- The FDA held a jointly sponsored Workshop on Medical Device Interoperability in 2010, which resulted in an MD PnP/industry working group that defined components of a prototype regulatory submission of a system of integrated medical devices, and formally submitted that document to the FDA. An updated version of that pre-submission will be submitted to the FDA in early 2014.

The majority of this award has been used for core personnel salary support, which provides the foundation to identify and access other available resources, to lead relevant standards work, and to build collaborations to achieve device interoperability objectives. These collaborations include activities and relationships with federal agencies; clinical, engineering, and IT societies; clinicians in the US, Canada, Europe, and Japan; and integrated healthcare delivery organizations like Kaiser Permanente, Johns Hopkins, Partners HealthCare, and the Veterans Health Administration.

Although we have been successful in attracting funding from several federal agencies (NIH, NSF, NIST), the funding is project-specific and does not support the standards work, convening,

and program infrastructure that the TATRC funding has so greatly enhanced. This work was also leveraged to expand projects such as the clinical scenario repository and the open source sharing of code into more detailed projects under new TATRC funding.

These activities are highly interdependent and synergistic, and TATRC support has been instrumental in providing the "program glue" to effectively leverage these synergies to realize our mutual program objectives.

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Appendices

None

Relevant documents are linked to from the text of the report.